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10/597,309

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Walid Ali

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS

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EXAMINER

BIEGEL, RONALD L

ART UNIT

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2857

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/597,309 | Applicant(s) ALI, WALID | |
| | Examiner Ronald L. Biegel | Art Unit 2857 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5,7-19,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-5,7-12 and 16-19 is/are allowed.
- 6) ☒ Claim(s) 13-15,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. **Claims 13-15, 21 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Thakor et al., "Multiway Sequential Hypothesis Testing for Tachyarrhythmia Discrimination" (pages 480-487): Item U in PTO-892, Notice of References Cited, in view of Palmer et al, Patent No: US 5,830,150 (hereinafter Palmer).

Regarding **claim 13**, Thakor teaches

employing hypothesis testing against each of a plurality of monitored signals (Thakor, pages 480-481, Sec. II, A) to determine whether an artifact is present in the plurality of monitored signals in which a null hypothesis includes an assumption that pairs of samples of correlated monitored signals of the plurality of monitored signals have a predetermined distribution (Thakor, page 481, left col. Ins 14-15); and determine that an artifact may exist in one of the plurality of monitored signals when a likelihood that the null hypothesis is true falls below a predetermined confidence level (Thakor, page 481, Top paragraph).

Thakor does not teach a plurality of leads, which receive a plurality of monitored signals; a plurality of leads which receive a plurality of monitored signals; a memory to

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store each of the received samples of the monitored signals; and a processor coupled to the memory.

Palmer teaches a plurality of leads which receive a plurality of monitored signals (Palmer, col 2, lns 5-8); a memory to store each of the received samples of the monitored signals (Palmer, col 2, ln 63-65); and a processor coupled to the memory (Palmer, col 2, ln 63-65).

It would have been obvious to one of ordinary skill in the art to combine Thakor with Palmer because Palmer provides the material means to implement the algorithm of Thakor thereby making its manufacture, sale and use possible for the medical profession and patients.

Regarding **claim 14**, Thakor and Palmer teach all the limitations of **claim 13**. Thakor teaches the processor is further programmed to: generate a probability that each of the monitored signals includes an artifact (Thakor, p 484, lines 6-8). (The examiner considers the "likelihood functions" of Thakor to be probability functions.)

Regarding **claim 15**, Thakor and Palmer teach all the limitations of **claim 14**. Thakor and Palmer do not teach a processor for generating an output signal to alert an operator that at least one of the monitored signals includes an artifact when the generated probability exceeds a predetermined threshold. Palmer teaches a processor for generating an output signal to alert an operator that at least one of the monitored signals includes an artifact when the generated probability exceeds a predetermined threshold (Palmer, col 2, ln 62-63). It would have been obvious to one of ordinary skill in the art to combine Thakor with Palmer because Palmer provides the material means to

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implement the algorithm of Thakor thereby making its manufacture, sale and use possible for the medical profession and patients.

Regarding **claim 21**, Thakor and Palmer teach all the limitations of **claim 13**.

Thakor teaches the predetermined distribution includes the same distribution as corresponding pairs of stored versions of the plurality of monitored signals (Thakor, page 482, Sec. III.B).

Regarding **claim 22**, Thakor and Palmer teach all the limitations of **claim 13**.

Thakor teaches a database which stores at least one of historical versions of the monitored signals and parameters of the historical versions of the monitored signals; and wherein the predetermined distribution includes a distribution of one of corresponding pairs of samples of historical versions of the monitored signals and the parameters of the historical versions of the monitored signals (Thakor, page 482, Sec. III.B).

Allowable Subject Matter

2. **Claims 3-5, 7-12 and 16-19** are allowed.
3. The following is an examiner's statement of reasons for allowance:

Claim 3 is allowed because the closest prior art, Thakor et al, ("Multiway Sequential Hypothesis Testing for Tachyarrhythmia Discrimination") and Palmer et al, (Patent No: US 5,830,150), either singularly or in combination, fail to anticipate or render obvious a method for monitoring a patient by employing hypothesis testing against each of the plurality of monitored signals to determine whether an artifact is present in the plurality of monitored signals, in which a null hypothesis includes an assumption that pairs of samples of correlated monitored signals of the plurality of monitored signals have a predetermined distribution, and the predetermined distribution including the same distribution as corresponding pairs of stored versions of the plurality of monitored signals and determining that an artifact

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may exist in one of the plurality of monitored signals when a likelihood that the null hypothesis is true falls below a predetermined confidence level.

Claim 9 is allowed because the closest prior art, Thakor et al, ("Multiway Sequential Hypothesis Testing for Tachyarrhythmia Discrimination") and Palmer et al, (Patent No: US 5,830,150), either singularly or in combination, fail to anticipate or render obvious a method for detecting an artifact by receiving one or more samples of a plurality of monitored signals carried on leads from a patient calculating, for each of the one or more samples of the plurality of monitored signals a cross probability of observing the sample and another sample assuming a null hypothesis is true, wherein the null hypothesis is that the sample and the other sample have a same distribution as a stored version of the sample of the plurality of monitored signals weighting each of the calculated cross probabilities so that samples being closer to a norm have a larger weight calculating a confidence level associated with each of the cross probabilities repeating the calculating steps for all combinations of pairs of highly correlated monitored signals of the plurality of monitored signals; summing, for each sample, all of the cross probabilities associated with a pair of correlated signals that includes the sample; and on a user interface device, outputting a result for each sample as a probability of not including an artifact in the sample, wherein if one or more of the probabilities of not including an artifact lies below a predetermined threshold, then indicating on the user interface that one or more samples associated with one or more of the probabilities may include an artifact.

Claim 11 is allowed because the closest prior art, Thakor et al, ("Multiway Sequential Hypothesis Testing for Tachyarrhythmia Discrimination") and Palmer et al, (Patent No: US 5,830,150), either singularly or in combination, fail to anticipate or render obvious a method for detecting an artifact by monitoring a plurality of monitored signals from one or more leads, extracting one or more samples of the plurality of monitored signals, calculating, for each of the one or more samples of the plurality of monitored signals, a cross probability of observing each sample and another sample assuming a null hypothesis is true, wherein the null hypothesis is that a combined distribution of the sample and the other sample have a predetermined distribution, calculating a confidence level associated with each of the cross probabilities, repeating the calculating steps for combinations of pairs of highly correlated monitored

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signals of the plurality of monitored signals summing, for each sample, a plurality of cross probabilities associated with a plurality of pairs of highly correlated signals, each of which includes a sample, outputting for each sample a result, wherein the result is obtained by subtracting the sum from one for each sample, as a probability of including an artifact in each sample, and on a display device, generating a display which indicates to an operator of the monitoring system, if one or more of the probabilities of including an artifact exceeds a predetermined threshold, then one or more samples associated with the one or more probabilities above the predetermined threshold may include an artifact.

Claim 16 is allowed because the closest prior art, Thakor et al, ("Multiway Sequential Hypothesis Testing for Tachyarrhythmia Discrimination") and Palmer et al, (Patent No: US 5,830,150), either singularly or in combination, fail to anticipate or render obvious for monitoring each of the one or more samples of the plurality of monitored signals a cross probability of observing each sample and another sample assuming a null hypothesis is true, wherein the null hypothesis is that the sample and the other sample have the same distribution as a stored version of the sample of the plurality of monitored signals, calculating a confidence level associated with each of the cross probabilities, repeating the calculating steps for all combinations of pairs of correlated monitored signals of the plurality of monitored signals summing, for each sample all of the cross probabilities associated with a pair of highly correlated signals that includes each sample, and outputting a result for each sample as a probability of not including an artifact in the sample, wherein if one or more of the probabilities of not including an artifact lies below a predetermined threshold indicating to a user that one or more samples associated with one or more of the probabilities may include an artifact.

Response to Argument

4. Applicant's arguments with respect to **claims 13-15, 21 and 22** have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald L. Biegel whose telephone number is (571) 272-

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2523. The examiner can normally be reached on 8:30-5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eliseo Ramos-Feliciano can be reached on (571) 272-7925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. B./
Examiner, Art Unit 2857

/Eliseo Ramos-Feliciano/
Supervisory Patent Examiner, Art Unit 2857